

Assembly Bill No. 467

Passed the Assembly April 1, 2014

Chief Clerk of the Assembly

Passed the Senate March 13, 2014

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2014, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add Section 4046 to, and to add Article 11.5 (commencing with Section 4169.5) to Chapter 9 of Division 2 of, the Business and Professions Code, and to amend Sections 150201, 150202, and 150205 of, and to add Section 150208 to, the Health and Safety Code, relating to pharmaceuticals, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 467, Stone. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which specified pharmacies and primary care clinics may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law authorizes specified health and care facilities, pharmacies, drug manufacturers, and pharmacy wholesalers to donate unused medications to the program. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating entity. Existing law exempts specified persons and entities, including prescription drug manufacturers and pharmacists and physicians who accept or dispense prescription drugs, from criminal and civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with these provisions.

Existing law, the Pharmacy Law, governs the scope and practice of pharmacy, including dispensing dangerous drugs and devices. Existing law establishes in the Department of Consumer Affairs the California State Board of Pharmacy to exercise licensing, regulatory, and disciplinary functions with respect to the practice of pharmacy. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, a continuously appropriated fund. A violation of the Pharmacy Law is a crime.

This bill would require the California State Board of Pharmacy to license a surplus medication collection and distribution intermediary, as defined, established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under the unused medication repository and distribution program described above. Among other things, the bill would prohibit that intermediary from taking possession, custody, or control of dangerous drugs and devices, but would authorize the intermediary to charge specified fees for the reasonable costs of the support and services provided. The bill would also require a surplus medication collection and distribution intermediary to keep and maintain for 3 years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities. The bill would require that a surplus medication collection and distribution intermediary license be renewed annually, and would require the payment of a fee in the amount of \$300 to obtain or renew the license. The bill would provide that the fees collected would be deposited in the Pharmacy Board Contingent Fund. By providing a new source of funds for a continuously appropriated fund, the bill would make an appropriation. Because a violation of the provisions governing licensing and recordkeeping would be crimes, the bill would impose a state-mandated local program. The bill would exempt a surplus medication collection and distribution intermediary from criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with these provisions.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4046 is added to the Business and Professions Code, to read:

4046. “Surplus medication collection and distribution intermediary” means a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision that performs the functions specified in Section 4169.5 for the purpose of a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code.

SEC. 2. Article 11.5 (commencing with Section 4169.5) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 11.5. Surplus Medication Collection and Distribution
Intermediaries

4169.5. (a) A surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code shall be licensed by the board. The board shall enforce the requirements set forth in Section 150208 of the Health and Safety Code. The license shall be renewed annually.

(b) An application for licensure as a surplus medication collection and distribution intermediary shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is an entity other than a natural person, the application shall state the information as to each person beneficially interested in that entity.

(c) As used in this section, and subject to subdivision (e), the term “person beneficially interested” means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(d) If the applicant is a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, the applicant shall furnish the board with the organization's articles of incorporation. The applicant shall also furnish the board with the names of the controlling members.

(e) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and if the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (b) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant's entity. Upon request by the executive officer of the board, the applicant shall furnish the board with the information required by subdivision (b) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(f) The application shall contain a statement to the effect that the applicant or persons beneficially interested have not been convicted of a felony and have not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(g) Upon the approval of the application by the board and payment of a fee in the amount of three hundred dollars (\$300), the executive officer of the board shall issue or renew a license to operate as a surplus medication collection and distribution intermediary, if all of the provisions of this chapter have been complied with. Fees received by the board pursuant to this section shall be deposited into the Pharmacy Board Contingent Fund. An applicant for licensure as a surplus medication collection and distribution intermediary that is government owned or is a nonprofit organization pursuant to subdivision (d) is exempt from the fee requirement.

(h) A surplus medication collection and distribution intermediary licensed pursuant to this section is exempt from licensure as a wholesaler.

(i) A surplus medication collection and distribution intermediary licensed pursuant to this section shall keep and maintain for three years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities.

SEC. 3. Section 150201 of the Health and Safety Code is amended to read:

150201. For purposes of this division:

(a) “Donor organization” means an entity described in subdivision (a) of Section 150202.

(b) “Eligible entity” means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(c) “Medication” or “medications” means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(d) “Participating entity” means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

SEC. 4. Section 150202 of the Health and Safety Code is amended to read:

150202. (a) Notwithstanding any other law, a donor organization is defined, for purposes of this division, to refer to one of the following health and care facilities that may donate centrally stored unused medications under a program established pursuant to this division:

(1) A licensed general acute care hospital, as defined in Section 1250.

(2) A licensed acute psychiatric hospital, as defined in Section 1250.

(3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(4) A licensed intermediate care facility, as defined in Section 1250.

(5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(7) A licensed correctional treatment center, as defined in Section 1250.

(8) A licensed psychiatric health facility, as defined in Section 1250.2.

(9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

(10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.

(11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

(b) Medication donated by health and care facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by the health and care facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the health or care facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

SEC. 5. Section 150205 of the Health and Safety Code is amended to read:

150205. (a) The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(1) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.

(2) A pharmacist or physician who accepts or dispenses prescription drugs.

(3) A licensed health or care facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.

(b) A surplus medication collection and distribution intermediary, as described in Section 150208, shall not be subject to criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with this division.

SEC. 6. Section 150208 is added to the Health and Safety Code, to read:

150208. (a) A surplus medication collection and distribution intermediary that is licensed pursuant to Section 4169.5 of the Business and Professions Code, established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to this division is authorized to operate under this section.

(b) A surplus medication collection and distribution intermediary shall comply with the following:

(1) It shall not take possession, custody, or control of dangerous drugs and devices.

(2) It shall ensure that notification is provided to participating entities that a package has been shipped when the surplus medication collection and distribution intermediary has knowledge of the shipment and provided logistical support to facilitate a shipment directly from a donor organization, as defined in subdivision (a) of Section 150202, to a participating entity.

(3) It shall not select, or direct a donor organization, as defined in subdivision (a) of Section 150202, to select, a specific participating entity to receive surplus medications.

(c) A surplus medication collection and distribution intermediary is authorized to do the following:

(1) Charge membership, administrative, or overhead fees sufficient to cover the reasonable costs of the support and services provided.

(2) Contract directly with a county to facilitate the donation of medications to or transfer of medications between participating

entities and provide general support in a county's implementation of a program established pursuant to this division.

(d) No participating entities shall receive donated medication directly from the surplus medication collection and distribution intermediary.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 8. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To ensure that California's medication donation program is allowed to continue to operate to facilitate the distribution of medications to the indigent population which would not otherwise have access to these medications, it is necessary that this act take effect immediately.

Approved _____, 2014

Governor